



## DEPARTMENT OF COMMERCE

### National Institute of Standards and Technology

#### Notice of NIST's Mouse Cell Line Authentication Consortium

AGENCY: National Institute of Standards and Technology

ACTION: Notice of Research Consortium

SUMMARY: The National Institute of Standards and Technology (NIST), an agency of the United States Department of Commerce, is establishing the Mouse Cell Line Authentication Consortium and invites organizations to participate in this Consortium. The Consortium will collaborate to obtain concordant short tandem repeat (STR) profiles for mouse cell lines, draft consensus standards for mouse cell line authentication, and create a public database of STR profiles for mouse cell lines. The Consortium has been developed in collaboration with American Type Culture Collection (ATCC). Participation in this Consortium is open to all eligible organizations, as described below.

DATES: NIST will accept responses for participation in this Consortium on an ongoing basis. The Consortium's activities will commence on or about December 15, 2016 ("Commencement

Date”). Acceptance of participants into the Consortium after the Commencement Date will depend on eligibility and the availability of testing reagents and other resources.

**ADDRESSES:** Information in response to this Notice and requests for additional information about the Consortium can be directed via mail to the Consortium Manager, Jamie Almeida, Biosystems and Biomaterials Division of NIST’s Material Measurement Laboratory, 100 Bureau Drive, Gaithersburg, Maryland 20899-8312, or via electronic mail to [jamie.almeida@nist.gov](mailto:jamie.almeida@nist.gov).

**FOR FURTHER INFORMATION CONTACT:** For further information about participation opportunities or about the terms and conditions of NIST’s Cooperative Research and Development Agreement (CRADA), please contact Honeyeh Zube, CRADA and License Officer, National Institute of Standards and Technology's Technology Partnerships Office, by mail to 100 Bureau Drive, Mail Stop 2200, Gaithersburg, Maryland 20899, by electronic mail to [honeyeh.zube@nist.gov](mailto:honeyeh.zube@nist.gov), or by telephone at (301) 975-2209.

**SUPPLEMENTARY INFORMATION:**

The estimated cost due to the use of misidentified and contaminated cell lines used in research exceeds millions of dollars. The authentication of cell lines is recommended by many journals and research funding entities prior to publication and funding, respectively. On June 9, 2015, the National Institute of Health issued a notice titled, “Enhancing Reproducibility through Rigor and Transparency” (NOT-OD-15-103) to address the revision of grant application instructions and grant review criteria to highlight the need to authenticate key biological materials, including cell lines. The NIH notice is available here: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD->

15-103.html. Currently, there is a consensus standard in place for human cell line authentication using short tandem repeat (STR) profiling which describes in detail the specific procedures to obtain reliable genotyping results. Databases of human STR profiles and commercial kits for human STR genotyping are also available. For non-human cell line authentication, however, there are no standards, STR genotyping kits, or databases available to researchers.

NIST researchers have developed a panel of STR markers specific to the mouse genus that can be used to discriminate among mouse cell lines. These STR markers are used in a multiplex polymerase chain reaction (PCR) assay and the PCR products are separated based on size using capillary electrophoresis (CE). This technology is the subject of a pending patent application owned by the United States Department of Commerce (US Patent Application Number 13/935,285).

The purpose of this Consortium is to draft guidance documents or consensus documentary standards that will delineate the definitive methods for mouse cell line authentication based on the data collected in a concordance study conducted as a part of the Consortium. These efforts will enable quality services to be provided for mouse cell line authentication. The Consortium is managed by NIST in collaboration with ATCC. NIST and ATCC will provide protocol test reagent kit and DNA samples from mouse cell lines to the Consortium members under specific terms and conditions. NIST will provide the Consortium members with a standard operating procedure (SOP) and genotyping kit which each Consortium member will be required to use to generate data for the mouse cell line DNA samples. The Consortium members will determine the parameters for data analysis and define the rules for interpretation of identity guided by the data collected. NIST will collect concordant STR profile data for each mouse cell line which will be used to build a public database for mouse cell lines. NIST will anonymize the data from

individual labs. NIST will share summaries of the data for all the mouse cell lines tested. NIST intends to publish the results of the research in the form of reports and publications in scientific journals with the members of the Consortium as co-authors, as appropriate.

**Participation Process:** Researchers at university core labs, at companies offering cell line authentication methods, at cell line repositories, and at other organizations that would benefit from mouse cell line authentication services, are invited to respond to this Notice to participate in this Consortium. Eligibility will be determined solely by NIST based on the information provided by interested organizations in response to this Notice on a first-come, first-serve basis to the extent that interested organizations are eligible and that testing reagents and other resources are available to accommodate additional participants. In order to be eligible to participate, the Consortium member will be required to have expert experience in STR genotyping, human cell line authentication, and CE operation. Additionally, the Consortium member will need to demonstrate that it has access to a thermal cycler and CE instrumentation, as required to complete the tasks in the SOP. Consortium members will be responsible for their own consumables for PCR and CE fragment analysis, except for the mouse STR kit and mouse cell line DNA, which will be provided by NIST and ATCC. NIST will evaluate the written responses to this Notice to determine eligibility to participate in this Consortium. Organizations responding to this Notice should provide the following information to NIST's Consortium Manager:

- (1) A description of the experience in cell line authentication, STR analysis, polymerase chain reaction (PCR), and STR genotyping software analysis. Please also indicate whether the organization offers cell line authentication services. Please also describe the methods and kits typically used by organization, and the number of years of

experience of the researchers at the organization who have been doing this type of work and who would be participating in this Consortium.

(2) Type of Instruments: The Consortium will provide STR profile concordance data for mouse cell lines. Please indicate the make and model of the thermal cycler and CE instrument that will be used to collect STR profile data. Also provide the type of polymer and array used for the CE instrument.

(3) Type of Software: Please indicate the type of software that will be used to analyze and generate electropherograms from the CE fragment data.

A responding organization may not include any business proprietary information in its response to this request for information. NIST will not treat any information provided in response to this Notice as proprietary information. NIST will notify each organization of its eligibility. All Consortium members will be required to sign the Cooperative Research and Development Agreement (CRADA) with NIST in order to participate in this Consortium. All Consortium members will be bound to the same terms and conditions.

Dated: October 7, 2016

Kevin Kimball,

Chief of Staff

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